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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/041,975	03/13/1998	MARC ALIZON	2356.0011-06	4167

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EXAMINER	
PARKIN, JEFFREY S	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/041,975	ALIZON ET AL.	
	Examiner	Art Unit	
	Jeffrey S. Parkin, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 23,25,44-46 and 48-56 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 23, 25, 44-46, and 48-56 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Office Action

Status of the Claims

Prosecution is hereby reopened as a result of the Pre-Appeal Brief Request. Claims 23, 25, 44-46, and 48-56 are currently under examination.

35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23, 25, 44-46, and 48-56 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Two separate requirements are set forth under this statute: (1) the claims must set forth the subject matter that applicants regard as their invention; and (2) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant. The claims have been amended to include a limitation specifying that the HIV-1 variant is capable of hybridizing under stringent conditions across the *entire* proviral LAV_{MAL} genome set forth in Figure 7. However, the claim allows for genetic variation up to ~22% in the *env* coding region. It is not readily manifest how nucleotide sequences displaying this degree of genetic unrelatedness would be capable of hybridizing under the recited reaction conditions. Appropriate clarification and correction are required.

The reference to a "direct sequence repeat" in claims 23, 25, 44-46, 51, and 53-56 is also vague and indefinite since the claims fail to set forth any meaningful nucleotide or amino acid sequence structural limitations that clearly set forth the metes and bounds of the patent protection desired. For instance, what is the composition and length of the repeat? Absent further clarification, the skilled artisan cannot readily ascertain the metes and bounds of the patent protection desired. Appropriate correction is required.

35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New Matter

Claims 23, 25, 44-46, and 48-56 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). The claims are directed toward purified HIV-1 variants displaying a certain amount of genetic unrelatedness at the amino acid sequence level (e.g., ~10-12% in Gag; ~5-8% in Pol; ~21-22% in Env). Additional functional limitations were also provided including some of the following: 1) The variant binds to antibodies present in AIDS patient sera; 2) The variant displays

the canonical genomic organization 5'-LTR-*gag-pol-vif-vpr-tat-rev-vpu-env-nef*-LTR-3'; 3) The variant hybridizes to a full-length proviral LAV_{MAL} genomic cDNA; and 4) The variant has at least one restriction site as set forth in Figure 1.

The disclosure only describes the molecular cloning and characterization of a single novel HIV-1 isolate, designated LAV-1_{MAL} or HIV-1_{MAL}. For example, the specification clearly states (bridging paragraph, pp. 2 and 3) that "a new virus has been discovered that is responsible for diseases clinically related to AIDS and that can be classified as a LAV-1 virus but that differs genetically from known LAV-1 viruses to a much larger extent than the known LAV-1 viruses differ from each other. The new virus is basically characterized by the cDNA sequence which is shown in Figures 7A to 7I, and this new virus is hereinafter generally referred to as LAV_{MAL}." The disclosure provides a restriction map for a molecular clone of HIV-1_{MAL} (see CHARACTERIZATION AND MOLECULE CLONING OF AN AFRICAN ISOLATE, pp. 7 and 8, and Figure 1). The complete nucleotide sequence and deduced amino acid sequence of this clone were ascertained (see Figure 7). The nucleotide sequence and deduced amino acid sequence of this novel isolate were compared to other known HIV-1 isolates (e.g., BRU, ELI, and ARV-2) (see Figures 1B-4 and 6). Based upon this comparison the inventors made three general conclusions. First, it was noted (specification, p. 10) that "the protein sequences of the LAV_{ELI} and LAV_{MAL} are more divergent from LAV_{BRU} that are those of HTLV-3 and ARV-2 (FIG. 4A)". Second, applicants reported that the *env* gene is more variable than the *gag* and *pol* genes. Third, it was reported that the divergence between LAV_{ELI} and LAV_{MAL} was comparable to that between LAV_{BRU} and each of the isolates. Thus, the skilled artisan would reasonably conclude that applicants have identified, cloned, and characterized a novel HIV-1 isolate designated MAL. The

skilled artisan would also reasonably conclude that applicants ascertained the genetic relatedness of this particular isolate to other known HIV-1 isolates such as HIV-1 ELI, BRU, and ARV-2. However, the skilled artisan would not reasonably conclude that applicants were in possession of any other HIV-1 variants, particularly one with the claimed limitations. The disclosure fails to provide any other molecular clones and their attendant nucleotide/amino acid sequences. The disclosure fails to identify the isolation, characterization, and nucleotide sequence of other variant HIV-1 MAL isolates. The disclosure fails to clearly identify the isolation, characterization, and preparation of viral variants with the recited properties. There is nothing in the disclosure that provides support for the specific limitations now being claimed. Thus, the applicants were clearly not in possession of the claimed subject matter at the time of filing and the claim language clearly represents an unwarranted attempt to capture subject matter that was clearly not invented by the applicants.

Written Description

Claims 23, 25, 44-46, and 48-56 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). *In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). *In re Rochester*, 358 F.3d 916, 69 U.S.P.Q.2d 1886 (C.A.F.C. 2004). The amended claims are directed toward purified HIV-1 variants displaying a certain amount of genetic unrelatedness at the amino acid sequence level (e.g., ~10-12% in Gag; ~5-8% in Pol; ~21-22% in Env). Additional functional limitations were also

provided including some of the following: 1) The variant binds to antibodies present in AIDS patient sera; 2) The variant displays the canonical genomic organization 5'-LTR-*gag-pol-vif-vpr-tat-rev-vpu-env-nef*-LTR-3'; 3) The variant hybridizes to a full-length LAV_{MAL} genomic cDNA; and 4) The variant has at least one restriction site as set forth in Figure 1.

As previously set forth, the crux of the statutory requirement governing written description is whether one skilled in the art, familiar with the practice of the art at the time of the filing date, could reasonably have found the later claimed invention in the specification as filed. *In re Kaslow*, 707 F.2d 1366, 1375, 217 U.S.P.Q. 1089, 1096 (Fed. Cir. 1983). *In re Wilder*, 736 F.2d 1516, 1520 222 U.S.P.Q. 349, 372 (Fed. Cir. 1984, *cert. denied*, 469 U.S. 1209 (1985). *Texas Instruments, Inc.* v. *International Trade Comm'n*, 871 F.2d 1054, 1063, 10 U.S.P.Q.2d 1257, 1263 (Fed. Cir. 1989). Moreover, the courts have stated that the evaluation of written description is highly fact-specific, and that broadly articulated rules are inappropriate. *In re Wertheim*, 541 F.2d 257, 263, 191 U.S.P.Q. 90, 97 (C.C.P.A. 1976). *In re Driscoll*, 562 F.2d 1245, 1250, 195 U.S.P.Q. 434, 438 (C.C.P.A. 1977). It is also important to remember that the true issue in question is not whether the specification enables one of ordinary skill in the art to make the later claimed invention, but whether or not the disclosure is sufficiently clear that those skilled in the art will conclude that the applicant made the invention having the specific claim limitations. *Martin* v. *Mayer*, 823 F2d 500, 505, 3 U.S.P.Q.2d 1333, 1337 (Fed. Cir. 1987).

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor has **possession** of the claimed invention. See, e.g., *Vas-*

Cath, Inc. v. *Mahurkar*, 935 F.2d at 1563, 19 U.S.P.Q.2d at 1116. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood* v. *American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997). The claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. *Fujikawa* v. *Wattanasin*, 93 F.3d 1559, 1571, 39 U.S.P.Q.2d 1895, 1905 (Fed. Cir. 1996).

The issue raised in this rejection is whether or not the disclosure supports the broad genus of HIV-1 variants currently being claimed. As previously set forth, and contrary to applicants' assertions, the disclosure only describes the molecular cloning and characterization of a single novel HIV-1 isolate, designated LAV-1_{MAL} or HIV-1_{MAL}. For example, the specification clearly states (bridging paragraph, pp. 2 and 3) that "a new virus has been discovered that is responsible for diseases clinically related to AIDS and that can be classified as a LAV-1 virus but that differs genetically from known LAV-1 viruses to a much larger

extent than the known LAV-1 viruses differ from each other. The new virus is basically characterized by the cDNA sequence which is shown in Figures 7A to 7I, and this new virus is hereinafter generally referred to as LAV_{MAL}." The disclosure provides a restriction map for a molecular clone of HIV-1_{MAL} (see CHARACTERIZATION AND MOLECULE CLONING OF AN AFRICAN ISOLATE, pp. 7 and 8, and Figure 1). The complete nucleotide sequence and deduced amino acid sequence of this clone were ascertained (see Figure 7). The nucleotide sequence and deduced amino acid sequence of this novel isolate were compared to other known HIV-1 isolates (e.g., BRU, ELI, and ARV-2) (see Figures 1B-4 and 6). Based upon this comparison the inventors made three general conclusions. First, it was noted (specification, p. 10) that "the protein sequences of the LAV_{ELI} and LAV_{MAL} are more divergent from LAV_{BRU} that are those of HTLV-3 and ARV-2 (FIG. 4A)". Second, applicants reported that the *env* gene is more variable than the *gag* and *pol* genes. Third, it was reported that the divergence between LAV_{ELI} and LAV_{MAL} was comparable to that between LAV_{BRU} and each of the isolates. Thus, the skilled artisan would reasonably conclude that applicants have identified, cloned, and characterized a novel HIV-1 isolate designated MAL. The skilled artisan would also reasonably conclude that applicants ascertained the genetic relatedness of this particular isolate to other known HIV-1 isolates such as HIV-1 ELI, BRU, and ARV-2. However, the skilled artisan would not reasonably conclude that applicants were in possession of any other HIV-1 variants, particularly one with the claimed limitations. The disclosure fails to provide any other molecular clones and their attendant nucleotide/amino acid sequences. The disclosure fails to identify the isolation, characterization, and nucleotide sequence of other variant HIV-1 MAL isolates. Thus, the applicants were clearly not in possession of the claimed subject matter at the time

of filing and the claim language clearly represents an unwarranted attempt to capture subject matter that was clearly not invented by the applicants.

It should be further noted that the *Lentivirinae*, particularly HIV-1, exists as a quasispecies (Li *et al.*, 1991; Groenink *et al.*, 1991; Daniels *et al.*, 1991; Delwart *et al.*, 1994). Because of the infidelity of the reverse transcriptase (RT) numerous viral copies are generated with different genotypic/phenotypic characteristics. Thus, the skilled artisan cannot predict *a priori* the nucleotide sequence of any given isolate before it is cloned and characterized. In fact, the skilled artisan would expect multiple molecular clones from the same individual to display considerable genetic heterogeneity. Thus, the skilled artisan cannot readily envisage the structure of any given variant. Moreover, many of the limitations set forth in the claim language fail to distinguish LAV_{MAL} variants from other HIV-1 variants. For instance, antibodies that bind to MAL will also bind to other HIV-1 isolates. Although the claims discuss antibodies that specifically bind to MAL, there is no description or discussion of antibodies in patient sera that recognize only MAl and not other isolates. Limitations directed toward the canonical genetic organization of LAV_{MAL} are not further limiting because all HIVs display the same genetic organization: 5'-LTR-*gag-pol-vif-vpr-tat-rev-vpu-env-nef*-LTR-3'. Finally, even at the claimed degrees of genetic unrelatedness, the claims encompass an inordinate number of species.[1] Clearly, applicants were not in possession of a representative number of species at the

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1 For instance, the Gag region alone could generate 1.5×10^{136} variants. This calculation is based upon 10% genetic variation across the entire Gag protein (505aa) and substitution with any one of the 19 naturally occurring amino acids. The Pol region alone could generate 1.1×10^{177} variants. This calculation is based upon 6% genetic variation across the entire Pol protein (1002aa) and substitution with any one of the 19 naturally occurring amino acids. The Env region alone could generate 1.7×10^{423} variants. This calculation is based upon 21% genetic variation across the entire Env protein (859aa) and substitution with

time of filing to support the full-breadth of the genus encompassed by the claim language.

Moreover, the courts have consistently stated that while applicants need not disclose every possible nucleic acid encoding any given protein, nevertheless, when attempting to capture a larger genus they must provide sufficient structural/functional guidance to support the full breadth of the claim language desired. *In re Wallach*, 71 U.S.P.Q.2d 1939 (Fed. Cir. 2004). In this situation, applicants have provided a single viral variant (LAV_{MAL}), but are attempting to capture a large genus encompassing genotypically/phenotypically diverse viruses. The disclosure fails to provide any guidance pertaining to those regions of Gag, Pol, and Env that are critical for viral replication. The disclosure is also silent pertaining to which regions of these structural proteins can tolerate genetic variation while maintaining wildtype function. Applicants have provided a single viral variant without providing any additional guidance pertaining to the genotypic/phenotypic characteristics of said virus. Accordingly, the skilled artisan would reasonably conclude that applicants were not in possession of the claimed invention at the time of filing.

Scope of Enablement

Claims 23, 25, 44-46, and 48-56 are rejected under 35 U.S.C. § 112, first paragraph, because the specification does not reasonably enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. As set forth *supra*, the claims are directed toward a large genus of HIV-1 variants. Specifically, the claims are directed toward purified HIV-1 variants displaying a certain amount of genetic unrelatedness at

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any one of the 19 naturally occurring amino acids.

the amino acid sequence level (e.g., ~10-12% in Gag; ~5-8% in Pol; ~21-22% in Env). Additional functional limitations were also provided including some of the following: 1) The variant binds to antibodies present in AIDS patient sera; 2) The variant displays the canonical genomic organization 5'-LTR-*gag-pol-vif-vpr-tat-rev-vpu-env-nef*-LTR-3'; 3) The variant hybridizes to a full-length proviral LAV_{MAL} genomic cDNA; and 4) The variant has at least one restriction site as set forth in Figure 1. The disclosure identifies a single HIV-1 variant designated LAV_{MAL}. Appropriately drafted claim language directed toward this embodiment would obviate the rejection.

The legal considerations that govern enablement determinations pertaining to undue experimentation have been clearly set forth. *Enzo Biochem, Inc.*, 52 U.S.P.Q.2d 1129 (C.A.F.C. 1999). *In re Wands*, 8 U.S.P.Q.2d 1400 (C.A.F.C. 1988). *Ex parte Forman* 230 U.S.P.Q. 546 (PTO Bd. Pat. App. Int., 1986). The courts concluded that several factual inquiries should be considered when making such assessments including the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art and the breadth of the claims. *In re Rainer*, 52 C.C.P.A. 1593, 347 F.2d 574, 146 U.S.P.Q. 218 (1965). The disclosure fails to provide adequate guidance pertaining to a number of these considerations as follows:

Excessive Claim Breadth

1) The claims are directed toward a large genus of HIV-1 variants that encompasses an inordinate number of species. For instance, if on considers the number of variants encompassed solely by variations in the Gag region, this would result in approximately

1.5×10^{136} variants. This calculation is based upon 10% genetic variation across the entire Gag protein (505aa) and substitution with any one of the 19 naturally occurring amino acids. The Pol region alone could generate 1.1×10^{177} variants. This calculation is based upon 6% genetic variation across the entire Pol protein (1002aa) and substitution with any one of the 19 naturally occurring amino acids. The Env region alone could generate 1.7×10^{423} variants. This calculation is based upon 21% genetic variation across the entire Env protein (859aa) and substitution with any one of the 19 naturally occurring amino acids. Thus, the claims clearly encompass an inordinate number of viral variants.

Lack of Working Examples

2) The disclosure fails to provide a sufficient number of working examples that would support the full breadth of the claim language desired. The only HIV-1 variant that is described in the specification is isolate MAL. No other variants were isolated, purified, and characterized to any appreciable extent.

Inadequate Guidance Provided

3) The disclosure also fails to provide sufficient guidance pertaining to those substitutions that are readily permissible. The claims encompass a considerable degree of genetic variation. However, the specification fails to provide any guidance or direction pertaining to which amino acid additions, deletions, or substitutions encompassed by the claim language will provide a replication-competent provirus and structural proteins that maintain their native configuration.

Unpredictability of the Art

4) It has been well-documented in the field of molecular retrovirology that single or multiple amino acid substitutions can have unpredictable effects on protein structure and function (Bosch and Pawlita, 1990; Boyer *et al.*, 1992; Yuan *et al.*, 1993). Single

amino acid substitutions can completely abrogate protein function. The claims allow for considerable genetic unrelatedness. However, the specification fails to provide sufficient guidance pertaining those amino acid substitutions that will preserve the integrity of the various structural proteins.

Accordingly, when all the aforementioned factors are considered *in toto*, it would clearly require undue experimentation from the skilled artisan to practice the claimed invention.

35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

35 U.S.C. § 103(a)

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 23, 25, 43-46, and 48-56 stand rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Myers *et al.* (1990). Applicants' again contend that the claims are fully supported by the disclosure and are entitled to the benefit of priority to earlier filed U.S. and French applications. As previously set forth, and contrary to applicants' assertion, this application clearly fails to provide an adequate written description of the claimed invention and priority cannot be extended under 35 U.S.C. § 119 or 120. Accordingly, the following art rejection is proper and hereby maintained. Myers *et al.* (1990) provide the complete nucleotide sequence of a novel purified HIV-1 isolate designated Z2Z6. This isolate is genetically related to the HIV-1 isolates ELI and MAL and appears to be only distantly related to the isolates BRU, IIIB (or HXB2), and ARV-2 (SF-2). Nucleotide sequence and amino acid analysis demonstrated that this isolate appears to vary from the aforementioned prototypical isolates BRU, IIIB, and ARV-2 by at least 3.4%, 3.1%, and 13.0% in the *gag*, *pol*, and *env* coding regions, respectively. Thus, this isolate appears to meet all the limitations of the claimed invention. Moreover, because of the

close genetic relatedness between Z2Z6 and the isolates ELI and MAL, one of ordinary skill in the art would reasonably expect nucleic acid probes and antibodies specific for MAL to also recognize Z2Z6 nucleic acids and antigens.

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Bruce R. Campell, Ph.D., can be reached at (571) 272-0974. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related correspondence to be: a) faxed to the Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or delivered to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing System. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information refer to the Updated Notice of Centralized Delivery and Facsimile Transmission Policy for Patent Related Correspondence, and Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

Jeffrey S. Parkin, Ph.D.
Primary Examiner
Art Unit 1648

06 August, 2007